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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,654	10/25/1999	EBERHARD AMMERMANN	47968	7539

26474 7590 08/16/2002

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EXAMINER
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ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 08/16/2002

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 17

Application Number: 09/403,654
Filing Date: October 25, 1999
Appellant(s): AMMERMANN ET AL.

Jason D. Voight
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6 May 2002.

(1) Real Party in Interest

BASF Aktiengesellschaft of Ludwigshafen, Germany.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that

there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 29-36, 39, 46 and 51 do not stand or fall together with claims 41-45, 49 and 50, and provides reasons as set forth in 37 CFR §§ 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection AND Response to Argument

The following ground(s) of rejection are applicable to the appealed claims:

(A) Claims 29-36, 39, 41-46 and 49-51 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 29-31 are broadly drawn to a process for producing a BAS 490F-tolerant plant, comprising transforming said plant with a gene encoding a monoclonal antibody polypeptide or a binding fragment thereof of any length and sequence. Claims 32-36 and 51 are broadly drawn to an expression cassette for transforming a plant comprising a gene encoding an exogenous BAS 490F-binding polypeptide or a part thereof produced according to claim 29, a selection marker comprising said expression cassette at claim 39 and a plant comprising said expression cassette at claim 46. Claims 29-36, 39, 46 and 51 are broadly drawn to processes of using and products comprising any gene encoding a BAS 490F-binding polypeptide derived from an antibody gene, which produces BAS 490F-tolerance in a plant. Claims 41-45 and 49 are broadly drawn to a process for the transformation of a plant or cell of a plant comprising introducing a gene sequence, which encodes any BAS 490F-binding peptide into said plant, or the cells of said plant.

Appellant does not describe the nucleotide sequence encoding the scFv-antiBAS 490F antibody fragment nor has Appellant deposited the disclosed scFv-antiBAS 490F

nucleotide sequence. In addition, Appellant has not described other BAS 490F-binding polypeptide encoding nucleotide sequences that would be required to practice the claimed invention. The specification only teaches the process of isolation of a single nucleotide sequence encoding a single monoclonal antibody (Example 2 on pages 19-20), but does not describe the resultant nucleotide sequence. There is no indication in the specification, nor in response to any of the previous Office Actions, that genes encoding antibodies to BAS 490F of the instant claims are readily identifiable or isolatable. In addition, there is no indication in the specification that other genes encoding BAS 490F binding antibodies are capable of conferring upon a transformed plant or a transformed plant cell, tolerance to BAS 490F as required by claims 39 and 46. In addition, the limitations of claims 41-45, 49 and 50 encompass gene sequences beyond those of BAS 490F antibody encoding gene sequences, and encompass all BAS 490F-binding polypeptides including receptors and enzymes such as cytochrome C oxidoreductase, which is the target of BAS 490F. Hence, there is a lack of written description for genes encoding other binding polypeptides, which are not specifically antibody encoding genes.

See *Amgen Inc. v Chagai Pharmaceutical co.*, 18 USPQ 2d 1016 (Fed. Cir. 1991), which teaches that the conception of a chemical compound requires the inventor to be able to define the compound so as to distinguish it from other materials, and to describe how to obtain it rather than simply defining it solely by its principle biological property; thus, when an inventor of a gene, which is a chemical compound albeit a complex one, is unable to envision detailed constitution of the gene so as to

distinguish it from other materials, as well as a method of obtaining it, the conception is not achieved until a reduction to practice has occurred, and until after the gene has been isolated.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See the Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday 5, 2001/ Notices; p. 1099-1111.

Appellant argues that the instant invention provides a completely novel way for producing herbicide/fungicide-resistant or –tolerant plants, and that the present invention is absolutely independent from the requirement of any detailed knowledge about endogenous mechanisms, gene expression or enzyme activity, but rather depends only on expression of an exogenous polypeptide, antibody or part of an antibody and recognition of an exogenous antigen, namely the herbicide (page 5 of the Brief on Appeal). Appellant argues that the scFv encoding nucleotide sequence itself is of minor importance to the invention and that claims 29-31, in particular, are not directed to "a DNA sequence", but rather to a process for producing a herbicide/fungicide-tolerant plant. Knowledge of a DNA sequence is not necessary to practice the invention, but rather the invention is practiced by carrying out the process steps set out

in the claims (last paragraph of page 7 to the 2nd paragraph of page 8 of the Brief on Appeal). Appellant quotes the MPEP "'[w]here the process has actually been used to produce the product, the written description requirement of a product-by-process claim is clearly satisfied'. MPEP 2163." (page 8, 2nd paragraph, lines 5-7 of the Brief on Appeal).

It is submitted that Appellant's arguments are not persuasive of error in the Examiner's position.

The Examiner notes that at claims 29-31, the claimed process is directed to producing a BAS 490F-tolerant plant by the method step of transforming a plant with a gene encoding a BASF-binding polypeptide, examples of said gene having not been adequately described in the instant specification to adequately demonstrate that Appellant was in possession of the invention as broadly claimed. MPEP section 2163 states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. Appellant's quote directed to MPEP 2163 is unclear. Appellant's quote does not appear to be within MPEP 2163. Irrespective of the origin of said quote, the Examiner responds that the process claimed by Appellant has not been

adequately described because a critical feature of the process, that being a gene encoding a BAS 490F-binding polypeptide has not been adequately described, and thus the process of using has not been adequately described. (see Written Description Guidelines, MPEP 2163 I(A. Original Claims)).

For the above reasons, it is submitted that the rejection should be sustained.

(B) Claims 29-36, 39, 41-46 and 49-51 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 29-31 are broadly drawn to a process for producing a BAS 490F-tolerant plant, comprising transforming said plant with a gene encoding a monoclonal antibody polypeptide or a binding fragment thereof of any length and sequence. Claims 32-36 and 51 are broadly drawn to an expression cassette for plants comprising a gene encoding an exogenous BAS 490F-binding polypeptide or a part thereof produced according to claim 29, a selection marker comprising said expression cassette at claim 39 and a plant comprising said expression cassette at claim 46. Claims 29-36, 39, 46 and 51 are broadly drawn to processes of using and products comprising any gene encoding a BAS 490F-binding polypeptide derived from an antibody gene, which produces BAS 490F-tolerance in a plant. Claims 41-45 and 49 are broadly drawn to a process for the transformation of a plant or cell of a plant comprising introducing a gene

sequence, which encodes any BAS 490F-binding peptide into said plant, or the cells of said plant.

The specification only provides guidance for a method of producing a BAS 490F-tolerant plant by transformation of a plant with a gene encoding an anti-BAS 490F antibody scFv fragment (see Example 2 on pages 19-20 of the specification). However, Appellant does not deposit the gene nor teach its nucleotide sequence, and hence Appellant does not provide sufficient guidance for another to practice the claimed invention.

Furthermore, the state of the art for DNA isolation requires guidance as to what sequences are critical for probe and PCR nucleotide sequence recovery methods, PCR reaction conditions and hybridization conditions. Appellant does not provide guidance for isolation of other nucleotide sequences encoding a polypeptide that binds BAS 490F nor does Appellant provide guidance for isolating the genus of nucleotide sequences, which encode peptides that bind BAS 490F, *e.g.*, the fungicide's target cytochrome c oxidoreductase, mutations thereof or fragments thereof. In addition, Appellant does not teach any other method of identifying and isolating BAS 490F-binding polypeptides and the nucleotide sequences that encode said polypeptides, other than that for the antibody scFv-antiBAS 490F, whose nucleotide sequence has not been taught.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of

working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would be required by one skilled in the art to identify a multitude of non-exemplified BAS 490F-binding proteins and to isolate the genes encoding them from a multitude of sources, and to evaluate the ability of these genes or a multitude of fragments thereof to confer tolerance in a multitude of transformed plants. In addition, undue experimentation would have been required to produce a multitude of BAS 490F-binding antibodies of a multitude of types, to identify and isolate genes encoding them from a multitude of sources, and to evaluate the ability of these genes or a multitude of fragments thereof to confer tolerance to BAS 490F in a multitude of plants.

Appellant argues that the present invention is absolutely independent from the requirement of biochemical or genetic information, only the availability of the herbicide as a chemical compound itself is sufficient to produce a herbicide-tolerant or -resistant transgenic plant (bottom of page 5, and page 9, 2nd paragraph, of the Brief on Appeal). Appellant argues that the instant application provides a person skilled in the art with the exact information for producing a fungicide-resistant or –tolerant plant (page 6, last sentence of the 1st paragraph, of the Brief on Appeal). Appellant argues that the scFv encoding nucleotide sequence itself and its disclosure is of minor importance to the underlying novel and inventive method (page 8, last sentence of the 1st paragraph, of

the Brief on Appeal). In summary, Appellant argues that the instant application provides a novel route and working guide for the general production of any kind of herbicide-tolerant or –resistant plant[s] and that knowledge of a DNA sequence is not necessary to practice the invention, but rather the invention is practiced carrying out the process steps set out in the claims.

Appellant argues that the Declaration of Andreas Reindl submitted 6 May 2002, a copy of that submitted 6 March 2002, provides evidence that one of ordinary skill in the art would have understood the process steps involved and been able to make and use the invention (bottom of page 9 of the Brief on Appeal). The Reindl Declaration outlines methods of isolating a gene encoding a monoclonal antibody known to one of ordinary skill in the [art]. Page 2 of the Reindl Declaration also states that the invention itself includes process steps for isolating a nucleotide sequence and said steps would have been understood by the skilled worker in the field, consequently, the disclosure of the nucleotide sequence is not necessary to make [and] use the invention.

It is submitted that Appellant's arguments are not persuasive of error in the Examiner's position.

The Examiner maintains that the likelihood of one of skill in the art reisolating the single specific scFv encoding nucleotide sequence of the instant invention is very remote. In addition, without a specific point of reference, such as the nucleotide sequence isolated in the instant specification, it would require undue trial and error experimentation by one of skill in the art at the time of the invention to isolate a myriad of BAS 490F-binding peptide encoding genes and to determine which gene, or fragment

thereof, would confer upon a transgenic plant BAS 490F-reistance or –tolerance, or which could be used as a selection marker as claimed. The Reindl Declaration has been considered, but is not persuasive because it merely provides general guidance for methods of producing antibody encoding genes and methods of transforming plants with those genes, which does not adequately enable the instant claims, in the absence of any specific guidance as to the particular gene being utilized.

For the above reasons, it is submitted that the rejection should be sustained.

Respectfully submitted,

DAVID T. FOX
PRIMARY EXAMINER
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David H Kruse, Ph.D.
July 31, 2002

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